

Activity Outline
FDA Drug Topics: Protecting Patients – Pharmacists Requirements under the Drug Supply Chain Security Act
May 8, 2018
FDA

Activity Coordinator
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Series Description

This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety.

Lecture Description

This webinar provides key requirements for dispensers (primarily pharmacies) under the Drug Supply Chain Security Act (DSCSA) for enhanced drug distribution security for protecting patients from receiving illegitimate prescription drugs, such as counterfeit or stolen drugs. The webinar will review current and future dispenser responsibilities under the law and highlight FDA resources available to dispensers to educate themselves further and stay up to date on the latest DSCSA implementation.

References

- The Drug Supply Chain Security Act (Title II of Public Law 113-54)
- Identifying Trading Partners Under the Drug Supply Chain Security Act Guidance for Industry
- DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information
- Standardization of Data and Documentation Practices for Product Tracing, Guidance for Industry
- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry
- Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry

Series Objectives

- Explain how to utilize FDA's Drug Information, medication safety resources, and regulatory guidances to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

Learning Objectives After completion of this activity, the participant will be able to:

- State goals and provide overview of the Drug Supply Chain Security Act (DSCSA)
- Review dispensers' current responsibilities under the DSCSA for product tracing, verification, and authorized trading partners
- Describe dispensers' future responsibilities under the DSCSA for product tracing and verification, utilizing the product identifier
- Summarize FDA resources for DSCSA law and policy, public meetings, webinars and implementation updates

Target Audience

This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, students and other healthcare professionals.

Agenda

Lecture 1 May 8, 2018

Time	Topic	Speaker
1:00 - 2:00 PM	Protecting Patients – Pharmacists Requirements under the Drug Supply Chain Security Act	Ilisa Bernstein Connie Jung

Continuing Education Accreditation



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In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.



IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-18-060-L03-P, and ACPE Universal Activity Number JA0002895-0000-18-060-L03-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacy participants: partial credit cannot be awarded, therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit

Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Bernstein, Ilisa, Deputy Director, CDER/Compliance - nothing to disclose
- Jung, Connie, Senior Advisor for Policy, FDA/CDER/Office of Compliance - nothing to disclose

Planning Committee

- Burke, Kara, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Navin, Lesley, RN, MSN, CSO, FDA/CDER/DDI - nothing to disclose
- Weinstein, Edward, M.D., Ph.D., Medical Officer, CDER FDA *My spouse received Salary from EndoCentre of Baltimore for*

a role as Employee.

CE Consultation and the Accreditation Team

- ▣ Gorinson, Justin, B.S., CHES, ORISE Fellow, FDA/CDER/OEP/DLOD - nothing to disclose
- ▣ Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- ▣ Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.